

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Tesfaye Biftu, et al.



Serial No. 10/556,805

Filed: November 14, 2005

For: 3-AMINO-4-PHENYLBUTANOIC ACID DERIVATIVES  
AS DIPEPTIDYL PEPTIDASE INHIBITORS FOR THE  
TREATMENT OR PREVENTION OF DIABETES

Art Unit: \_\_\_\_\_

Examiner: \_\_\_\_\_

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK &amp; CO., INC.

By Pamela Spaulding Date 8-24-07

# INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

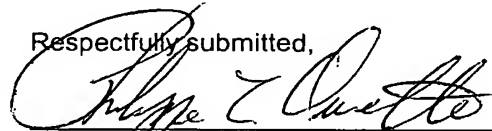
RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☐ the attached information is filed within three months of the filing date of the captioned case.
- ☒ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application *and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.*
- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,



By: Philippe L. Durette

Attorney \_\_\_\_\_ For Applicant(s)

Reg. No. 35,125

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594-4568

Date: August 24, 2007

*(use as many sheets as necessary)*

**COMPLETE IF KNOWN**

<b>Application Number</b>	10/556,805
<b>Filing Date</b>	November 14, 2005
<b>First Named Inventor</b>	Tesfaye Biftu
<b>Group Art Unit</b>	
<b>Examiner Name</b>	

14, 2005

STU ET AL

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AUG 27 2007

PATENT & TRADEMARK OFFICE

Sheet	1	of	4	Attorney Docket Number	21404P
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Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
	1	PCT	WO 97/40832		Hans-Knoll-Institut Fur Naturstoff-Forschung E. V.	11/06/1997
	2	PCT	WO 98/19998		Novartis AG	05/14/1998
	3	PCT	WO 00/34241		Novartis AG	06/15/2000
	4	PCT	WO 01/34594 A1		Guilford Pharmaceuticals, Inc.	05/17/2001
	5	PCT	WO 01/42262 A2		Akzo Nobel N.V.	06/14/2001
	6	PCT	WO 01/96295 A2		Novartis AG	12/20/2001
	7	PCT	WO 02/02560 A2		Novo Nordisk A/S	01/10/2002
	8	PCT	WO 02/076450 A1		Merck & Co., Inc.	10/03/2002
	9	PCT	WO 03/000180 A2		Merck & Co., Inc.	01/03/2003
	10	PCT	WO 03/000181 A2		Merck & Co., Inc.	01/03/2003

Examiner  
Signature

Date  
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\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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<b>Filing Date</b>	November 14, 2005
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<b>Group Art Unit</b>	
<b>Examiner Name</b>	

Sheet	2	of	4	Attorney Docket Number	21404P
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## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
	11	PCT	WO 03/082817 A2		Merck & Co., Inc.	10/09/2003
	12	PCT	WO 2004/007468 A1		Merck & Co., Inc.	01/22/2004
	13	PCT	WO 2004/032836 A2		Merck & Co., Inc.	04/22/2004
	14	PCT	WO 2004/043940 A1		Merck & Co., Inc.	05/27/2004
	15	PCT	WO 2004/050022 A2		Merck & Co., Inc.	06/17/2004
	16	PCT	WO 2004/058266 A1		Merck & Co., Inc.	07/15/2004
	17	PCT	WO 2004/064778 A2		Merck & Co., Inc.	08/05/2004
	18	PCT	WO 2004/069162 A2		Merck & Co., Inc.	08/19/2004
	19	PCT	WO 2004/110436 A1		Merck & Co., Inc.	12/23/2004
	20	PCT	WO 2004/112701 A2		Merck & Co., Inc.	12/29/2004

**Examiner  
Signature**

Date  
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<b>Application Number</b>	10/556,805'
<b>Filing Date</b>	November 14, 2005
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<b>Examiner Name</b>	

Sheet	3	of	4	Attorney Docket Number	21404P
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Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
	21	PCT	WO 2005/011581 A2		Merck & Co., Inc.	02/10/2005
	22	PCT	WO 2005/044195 A2		Merck & Co., Inc.	05/19/2005
	23	PCT	WO 2005/056003 A1		Graffinity Pharmaceuticals AG	06/23/2005
	24	PCT	WO 2005/056013 A1		Graffinity Pharmaceuticals AG	06/23/2005
	25	PCT	WO 2005/108382 A1		Merck & Co., Inc.	11/17/2005
	26	PCT	WO 2005/116029 A1		Merck & Co., Inc.	12/08/2005
	27	PCT	WO 2005/123685 A1		Astrazeneca AB	12/29/2005

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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE</b>  <b>STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>COMPLETE IF KNOWN</b>	
				Application Number	10/556,805
				Filing Date	November 14, 2005
				First Named Inventor	Tesfaye Biftu, et al
				Group Art Unit	
				Examiner Name	
Sheet	4	of	4	Attorney Docket Number	21404P

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	1	Augustyns, K. et al., "Dipeptidyl peptidase IV inhibitors as new therapeutic agents for the treatment of Type 2 diabetes" Expert Opin. Ther. Patents, Vol. 13, No. 4, pp 499-510, 2003
	2	Augustyns, K. et al., "Inhibitors of proline-specific dipeptidyl peptidases: DPP IV inhibitors as a novel approach for the treatment of Type 2 diabetes" Expert Opin. Ther. Patents, Vol. 15, No. 10, pp 1387-1407, 2005
	3	Deacon, C. F., "Perspectives in Diabetes - Therapeutic Strategies Based on Glucagon-Like Peptide 1" Diabetes, Vol. 53, pp 2181-2189, 2004
	4	Deacon, C. F. et al., "Inhibitors of dipeptidyl peptidase IV: a novel approach for the prevention and treatment of Type 2 diabetes?" Expert Opin. Investig. Drugs, Vol. 13, No. 9, pp 1091-1102, 2004
	5	Drucker, D. J., "Therapeutic potential of dipeptidyl peptidase IV inhibitors for the treatment of type 2 diabetes" Expert Opin. Investig. Drugs, Vol. 12, No. 1, pp 87-100, 2003
	6	Holst, J. J., "Treatment of Type 2 diabetes mellitus with agonists of the GLP-1 receptor or DPP-IV inhibitors" Expert Opin. Emerg. Drugs, Vol. 9, No. 1, pp 155-166, 2004
	7	Knudsen, L. B., "Glucagon-like Peptide-1: The Basis of a New Class of Treatment for Type 2 Diabetes" J. Med. Chem, Vol. 47, pp 4128-4134, 2004
	8	Novartis AG: WO0034241 - "Novel N-substituted-2-cyanopyrrolidines as potent inhibitors of dipeptidyl peptidase IV in the treatment of non-insulin-dependent diabetes mellitus", Exp. Opin. Ther. Patents, Vol. 10, No. 12, pp 1937-1942, 2000
	9	Vahl, T. P. et al., "Gut peptides in the treatment of diabetes mellitus", Expert Opin. Investig. Drugs, Vol. 13, No. 3, pp 177-188, 2004
	10	Holst, J. J. et al., "Glucagon-like peptide 1 and inhibitors of dipeptidyl peptidase IV in the treatment of type 2 diabetes mellitus" Current Opinion in Pharmacology, Vol. 4, pp 589-596, 2004
	11	Demuth, H. U. et al., "Type 2 diabetes-Therapy with dipeptidyl peptidase IV inhibitors" Biochimica et Biophysica Acta, Vol. 1751, pp 33-44, 2005
	12	Weber, A. E., "Dipeptidyl Peptidase IV Inhibitors for the Treatment of Diabetes" J. Med. Chem, Vol. 47, pp 4135-4141, 2004

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**P&T OFFICE ACKNOWLEDGEMENT**

ATTORNEY	DATE
Philippe L. Durette	8/24/2007
CASE NUMBER/	SERIAL NUMBER
21404P	10/556,805
DATE FILED	
November 14, 2005	
APPLICANT	
Teskaye Biftu, et al.	
EXPRESS MAIL NO.	

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The Patent & Trademark Office acknowledges, and has stamped hereon, the date of the receipt of the items checked below:

- ☐ AMENDMENT
- ☐ APPEAL AND FEE
- ☐ BRIEF
- ☐ CERTIFICATE OF CORRECTION
- ☐ FINAL FEE
- ☐ LETTER
- ☒ INFORMATION DISCLOSURE STATEMENT
- ☒ PTO 1449 & REFERENCES - **39 References**
- ☐ PETITION FOR EXTENSION OF TIME & FEE
- ☐ INVITATION TO CORRECT
- ☐ DEMAND-CHAPTER II & FEE SHEET
- ☐ SEQUENCE STATEMENT
- ☐ SEQUENCE LISTING
- ☐ SEQUENCE DISKETTE